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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/557,187	04/21/00	BAKER	425802800200

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EXAMINER

YU, G

ART UNIT

1619

PAPER NUMBER

DATE MAILED: 05/23/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

# Office Action Summary

Application No.

09/557,187

Applicant(s)

BAKER, AMY E.

Examiner

Gina C Yu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 31 July 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1-20.
- 18) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

(A) Claims 1, 6, 7, 8, 10-12, 16-17 and 20 are rejected under 35 U.S.C. 102(a) and 102(e) as being anticipated by Biedermann et al. (U.S. Pat. No. 6,150,403).

Biedermann et al. describe topical compositions for reducing oily appearance on skin, which comprise anti-acne agents. The reference teaches that the composition may comprise 0.05 – 10% of the anti-acne agents, wherein the anti-acne agents may be salicylic acid. See col. 8, lines 13 – 50. The reference further teaches that the composition may comprise a dermatologically acceptable carrier in the form of sprays and aerosols, wherein the carriers may be alcohol and water. See col. 12, line 19 – col. 13, line 19. The reference also teaches that the combination of cetyl betaine and salicylic acid is preferred, which meets claim 6.

(B) Claims 1, 7-12, 16-18 and 20 are rejected under 35 U.S.C. § 102(a) and (e) as anticipated by O'Halloran et al. (U.S. Pat. No. 6,168,798 B1).

O'Halloran et al. describe non-irritating compositions for treating acne and related skin disorders, containing 0.1-15% by weight of ketatolytic compound, 5-55% of alcohol, and 50-

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90% of water. See col. 2, line 23 – col. 3, line 27. See also claims. The reference teaches that the composition may be used in the form of aerosol sprays. See col. 6, lines 1 – 8. Example 1 illustrates the formulation for a non-irritating cosmetic astringent, comprising 30% by weight of denatured alcohol, 66.14% of water, and 0.52% of salicylic acid. See col. 8, lines 33 – 48. The reference teaches that the composition is nongreasy, leaves no residue upon application, and dries quickly. See col. 7, line 61 – col. 8, line 7.

Examiner takes denatured alcohol as an interchangeable term for denatured ethanol.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

(A) Claims 3-5 and 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Biedermann et al. (U.S. Pat. No. 6,150,403) in view of Guang Lin et al. (U.S. Pat. No. 5,612,321)

Biedermann is discussed above. The reference lacks the teaching of the pH of the solution.

Guang Lin et al. describe methods for treating acne with salicylic acid and pantothenic acid or its derivative. The composition in the reference comprise 0.01 – 20% by weight of salicylic acid, dexpanthenol, and a carrier, wherein the preferred carrier is a mixture of 20-50%

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of ethanol, isopropanol or mixtures thereof, and 50-80% of water, which meets claims 7 and 8. See col. 2, lines 45 – 56; col. 5, lines 55 – 67. The reference also teaches that the pH range for the composition should be such that the ionization of the salicylic acid is suppressed while the solution readily penetrates the skin. See col. 3, line 54 – col. 4, line 18. Claims 3-6 are met by the disclosure that the preferred pH range for the composition is 2 to 7. See col. 4, lines 13 – 17. The reference further suggests formulating the composition into a dispenser, suggesting the use of the composition in the form of spray. See col. 8, lines 29-58.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the spray composition in Biedermann et al. by adjusting the pH of the solution within the disclosed range in Guang Lin because of the expectation to have produced the salicylic acid solution with suppressed ionization and enhanced penetration, as taught by Guang Lin.

(B) Claims 2, and 19 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Biedermann et al. in view of Sciarra (Remington: Practice of Science and Pharmacy, 19<sup>th</sup> Ed., p. 1776 – 1692.).

Biedermann et al. is discussed above. The reference lacks a teaching on the liquid particle size of the spray and the quantity of the dispensed liquid per actuation.

Sciarra teaches that topical aerosols have been used for preparations for the treatment of acne. See p. 1676, 1<sup>st</sup> par. He also teaches that for topical sprays particles are produced in size from 50-200  $\mu\text{m}$ , which meets claim 2. See p. 1677, 4<sup>th</sup> par. It is further disclosed that for a typical metered-dose aerosol delivery system for pharmaceuticals, the size of the chamber can be

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modified so that about 25-150  $\mu$ L of the solution can be delivered per actuation, which meets claim 19. See p. 1688, 6<sup>th</sup> par. – p. 1689, 1<sup>st</sup> par.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the spray in Biedermann et al. by employing the spray system in Sciarra because of the expectation to have produced a conventional topical spray suitable for pharmaceutical use, as taught by Sciarra.

(C) Claim 13 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Biedermann et al. in view of Rhea (U.S. Pat. No. 5,195,664).

Biedermann et al. is discussed above. The references lacks a mention of using the spray container as described in claim 13.

Rhea discloses all directional fluid pick up for spray containers, which meets claim 13. See col. 2, line 63 – col. 3, line 55; col. 4, line 14 – col. 7, line 43.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the spray in Biedermann et al. by employing the dispensing system in Rhea because of the expectation to have produced a topical spray that may be used from all positions, as suggested by Rhea.

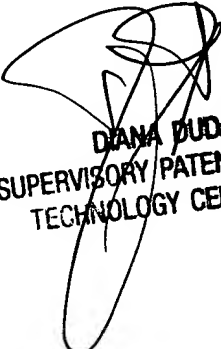
The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 703-305-3593.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana Dudash can be reached on 703-308-2328. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Gina C. Yu  
Patent Examiner  
May 17, 2001



**DIANA DUDASH**  
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